REMARKS

Upon amendment, Claims 1-4, 6, and 11-14 are pending in the instant application. Claims 5 and 7-10 have been canceled herein, without prejudice. Claim 1 has been amended to recite "or a salt thereof" instead of "and the salts, solvates or solvates of the salts thereof." Claim 6 has been amended to recite "a pharmaceutical composition" instead of "a medicament." No new matter has been added by these amendments.

Claims 11-14 are new and are directed to methods of controlling a viral infection in a human or an animal (Claim 11) and to a method of treating a viral infection in a human or animal (Claims 12-14). Support for these new claims can be found throughout the specification and claims as originally filed; in particular, in original Claims 7, 8 and 10, and at Pages 27-29 of the specification. No new matter has been added by these claims.

Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the application is believed to be in condition for allowance.

Claim Objections

Claim 10 was rejected as being in improper multiple dependent form. Claim 10 has been rewritten as Claim 11 which depends only from Claims 1 and 6. As such, the objection is moot.

Rejections under 35 U.S.C. §101

Claims 7 and 8 were rejected under 35 USC § 101, as related to a use without setting forth any steps. Claims 5 and 7-9 have been rewritten as method of treatment Claims 12-14. As such, the rejection is moot.

Rejections under 35 U.S.C. §112 , first paragraph

Claims 1-9 are rejected under 35 USC § 112, first paragraph, as allegedly failing to comply with the enablement requirement concerning solvates or solvates of salts.

While Applicants strongly disagree with the Examiner's allegation, and solely for the purpose of advancing prosecution, Claim 1 has been amended to recite "or a salt thereof" instead of "and the salts, solvates or solvates of the salts thereof." As such, the rejection to these claims is moot.

Claims 5 and 9 are further rejected as allegedly failing to comply with the enablement requirement concerning prevention of viral infection or prophylaxis.

Again, while Applicants strongly disagree with the Examiner's allegation, and solely for the purpose of advancing prosecution, Claims 5 and 9 have been canceled without prejudice and have been rewritten the treatment claims which do not recite prevention or prophylaxis. Applicants have done this solely to expedite the prosecution of the present application, and without prejudice to Applicants right to pursue them in one or more continuation, divisional or continuation-in-part applications. As such, the rejection to these claims is moot.

Finally, on Page 8 of the Office Action, the Examiner appears to have questioned the enablement of the treatment of the diseases and viral infections claimed in claims 5 and 9. As mentioned above, Claims 5 and 7-9 have been rewritten as method of treatment claims 12-14. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.,* 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *Manual of Patent Examining Procedure* ("MPEP") § 2164.04 (citing *In re Wright,* 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Accordingly:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement* ... unless there is a *reason to doubt the objective truth of the statements* contained therein which must be relied on for enabling support
>
> * * *

> It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.

Id. (emphases added).

Applicants respectfully submit that whether or not the scope of a claim is broad is irrelevant to the assessment of the enablement of the claim. The question is whether those skilled in the art would have been able to make and use the claimed invention based on the disclosure. *(See U.S. v. Telectronics, Inc.,* at 785).

Applicants respectfully submit that the pending claims are enabled because the specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

For example, the specification teaches that the compounds of the present invention are useful in that "the compounds of the invention of the general formula (I) show a surprising range of effects which could not have been predicted. They show an antiviral effect on representatives of the group of Herpes viridae (herpes viruses), in particular on cytomegaloviruses (CMV) especially on human cytomegalovirus (HCMV). They are therefore suitable for the treatment... of diseases, especially of infections with viruses, in particular the aforementioned viruses, and the infectious diseases caused thereby...The compounds of the formula (I) can, because of their particular properties, be used to produce medicaments which are suitable for the ... treatment of diseases, especially viral infections. Areas of indication which may be mentioned by way of example are: 1) Treatment and prophylaxis of HCMV infections in AIDS patients (retinitis, pneumonitis, gastrointestinal infections). 2) Treatment and prophylaxis of cytomegalovirus infections in bone marrow and organ transplant patients who develop often life-threatening HCMV pneumonitis or encephalitis, and gastrointestinal and systemic HCMV infections. 3) Treatment and prophylaxis of HCMV infections in neonates and infants. 4) Treatment of an acute HCMV infection in pregnant women. 5) Treatment of HCMV infection in immunosuppressed patients associated with cancer and cancer therapy. 6) Treatment of HCMV-positive cancer patients with the aim of reducing HCMV-mediated tumour progression (cf. J. Cinatl, et al., FEMS Microbiology Reviews 2004, 28, 59-77)." (Pages 27-28).

Similarly, it is disclosed that the claimed compounds can be prepared by synthetic procedures described in the scheme presented on Page 27 and in the Examples.

Finally, the specification discloses various tests and assays which can be readily performed by one of ordinary skill in the art to determine the desired activity without undue experimentation (Pages 116-118). Therefore, it is clear that a sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention, as required by 35 U.S.C. § 112, first paragraph.

Applicants respectfully assert that sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention. Indeed, the claimed invention is directed to the use of obtainable compounds. The skilled artisan can readily determine the activity for any of the compounds encompassed by the claims by using the assays described in the specification, which can be readily used to determine that a synthesized compound is useful in the treatment of the diseases recited in the claims. Moreover, the determination by a physician as to whether a claimed compound is effective in treating a recited disease in a given patient is a type of determination that is always made by physicians for every pharmaceutical. Indeed, the determination is a routine one that every physician is prepared to make, and which requires little or no effort. Therefore, Applicants respectfully submit that one reasonably skilled in the art could make or use the invention as claimed without undue experimentation.

In sum, Applicants respectfully submit that the specification provides sufficient information and guidance to those of ordinary skill in the art to make and use the claimed invention and to the extent any experimentation is necessary, such experimentation is not undue. Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

CONCLUSION

In view of the foregoing, reconsideration and withdrawal of all rejections, and allowance of the instantly claimed invention is earnestly solicited. If a telephone conversation with Applicants' attorney would help expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' attorney at the telephone number below.

Applicants believe that there are no additional fees due with this response. However, if a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 04-1105 for any fee(s) due with this response.

Dated: June 29, 2009

Respectfully submitted,

Electronic signature: /Nicholas J. DiCeglie, Jr./
Nicholas J. DiCeglie, Jr.
Registration No.: 51,615
Edwards Angell Palmer & Dodge LLP
P.O. Box 55874
Boston, Massachusetts 02205
(212) 308-4411
Attorneys/Agents For Applicant

Customer No. 35969